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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,924	12/19/2001	Yanagita Toshihiko	YAM 2 0013	8207

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/01/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,924

Applicant(s)

TOSHIHIKO, YANAGITA

Examiner

Sheridan K Snedden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13 and 15-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 15-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

1. This Office Action is in response to Paper #8, filed 26 June 2003. Claims 1-12 and 14 have been canceled. Applicant's amendment of claim 13 is acknowledged. Applicant's addition of new claims 15-34 is acknowledged. Claims 13 and 15-34 are under examination.

***Withdrawal of Objections and Rejections***

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 15-19, and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramakrishnan *et al.* (US Pub 2001/0041355 A1). Ramakrishnan *et al.* teach a method of treating urinary incontinence with an agent that modulates the nerve growth factor-related G protein-coupled receptor (NF-GPCR) (see section [0031]; claim 62). Ramakrishnan *et al.* teach that adrenomedullin (regarding claims 15-19 and 26-29) is a natural ligand of NGFR-GPCRs (see section [0144]). Thus, the reference anticipates the claimed method.

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***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishnan *et al.* (US Pub 2001/0041355 A1) in view of Kitamura *et al.* (US Patent 5,910,416).

Ramakrishnan *et al.* teach a method of treating urinary incontinence with an agent that modulates the nerve growth factor-related G protein-coupled receptor (NF-GPCR) (see section [0031]; claim 62). Ramakrishnan *et al.* teach that adrenomedullin (regarding claims 15-19 and 26-29) is a natural ligand of NGFR-GPCRs (see section [0144]). Ramakrishnan *et al.* do not teach the modification to adrenomedullin as recited in claims 20-24 and 30-34.

Kitamura *et al.* adrenomedullin as a novel hypotensive peptide. Kitamura *et al.* teach the intravenous administration of a composition comprising adrenomedullin (see figure 3). The composition of Kitamura *et al.* comprises the peptide having the amino acid sequence from Ser13 to Tyr52, Tyr1 to Tyr52, Ala(-73) to Tyr52, and Met(-94) to Leu91 of SEQ ID NO: 2. In one embodiment of the above peptide, the carboxyl terminus of the peptide is amidated (see column 1, lines 66 and 67). In one embodiment of the above peptide, Gly is attached to the carboxyl terminus of the N-terminal peptide of proadrenomedullin (see column 2, lines 1 and 2). In one embodiment of the above peptide, Cys in the 16 position and Cys in the 21 position of SEQ ID No. 1 are linked by a disulfide bond, which may be substituted with a -CH<sub>2</sub>-CH<sub>2</sub>-

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bond (see column 2, lines 8-13). Kitamura *et al.* teach that adrenomedullin, and the modified versions above, have a hypotensive effect and a vasodilating effect, and therefore, they are useful in the treatment of a disease. Kitamura *et al.* provide the examples of hypertension and cardiac incompetence but fail to specifically provide an example of a urinary disorder.

Taken together, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the modified adrenomedullin as taught by Kitamura *et al.* for the purposes of treating urinary incontinence as taught by Ramakrishnan *et al.* A person of ordinary skill in the art would have been motivated to make the above substitution because Kitamura *et al.* suggest that the modified adrenomedullin may be used as treatment in diseases alleviated by their hypotensive effect and a vasodilating effect. The person of ordinary skill in the art would have expected success because Ramakrishnan *et al.* demonstrated that adrenomedullin could be used in a method of treating urinary incontinence

### ***Conclusion***

5. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
September 23, 2003

SKS

  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER